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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/021,421	02/10/1998	RUSSEL T. JORDAN	399037	4431

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/021,421	JORDAN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,14-21,34-36 and 39-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14-21,34-36 and 39-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Informalities

1. Claims 1-7, 14-21, 34-36 and 39-50 are pending in this application.

2. Acknowledgement is made of Applicant's Amendments dated 12/16/2005.

Double Patenting

3. Claims 1-7, 14-21, 34-36, and 39-50 are again provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/247,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons given in the Paper of April 26, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted that Applicant's have not argued this rejection, but appear to acquiesce it.

The above referenced Application (10/247,161) is now allowed although no Patent Number or Issue Date has been assigned to it. This obvious-type double patenting rejection will become Non-Provisional upon issuance of the patent to Application 10/247,161.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or

unpredictability or the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount of *prima facie* case is discussed below.

4. Claim 19 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification, while being enabling for nordihydroguiaretic acid and ascorbic acid as antioxidants, does not reasonably provide enablement for the carrier containing any general nor all "means for functioning" as an antioxidant. The Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) The quantity of experimentation necessary,

2) The amount of direction or guidance provided,

3) The presence or absence of working examples,

4) The nature of the invention,

5) The state of the prior art,

6) The relative skill of those in the art,

7) The predictability of the art, and

8) The breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth below:

1. The quantity of experimentation necessary

The Specification does not disclose what "means for functioning" would be included in enabling the carrier to function as an antioxidant. It would take undue experimentation to determine the "means for functioning" that would yield the desired result of enabling the carrier to function as an antioxidant while also yielding the desired activity and safety of the composition.

The burden of enabling the any and all "means for functioning" as an antioxidant (i.e. the need for additional testing) would be greater than that of enabling a specific antioxidant such as nordihydroguiaretic acid or ascorbic acid. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about determining exactly what antioxidants can be used as carriers in the instant composition. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy and safety of the presently claimed method when other antioxidants aside from nordihydroguiaretic acid and ascorbic acid are used. Specifically, it is highly unlikely, and the Office would require experimental evidence to a claim such as that of Claim 19, which claims that any means for functioning as an antioxidant can be used as a carrier, for example.

2. The amount of direction or guidance provided

The specification provides no direction for ascertaining how one would go about formulating a carrier with a general "means for functioning as antioxidant" and the applicant has not demonstrated that the composition wherein the antioxidant is eugenol, for example, can reasonably be expected, *a priori*, to exhibit the requisite efficacy, safety, and stabilizing effect on chelated 8-hydroxyquinoline needed by the composition for treatment of human subjects. Further, Applicant has provided no guidance on how any and all "means for functioning as an antioxidant" can be used in the compositions recited in the instant claims.

3. Presence or absence of working samples

Only a limited selection of specified compositions containing an antioxidant (nordihydroguiaretic acid) are enumerated by the specification and the working examples are even more limited. Although the applicant has demonstrated how one would formulate a composition containing nordihydroguiaretic acid as the antioxidant, they have not provided any working examples demonstrating the use of any other antioxidants.

4. The nature of the invention

The claimed invention relates to compositions containing 8-hydroxyquinoline, $ZnCl_2$, and a carrier, wherein the carrier can contain any means for functioning as an antioxidant. The purpose of the antioxidant, as described in the Specification, is to stabilize chelated 8-hydroxyquinoline.

5. State of the prior art

The prior art describes the use of nordihydroguiaretic acid and ascorbic acid as antioxidants that can stabilize chelated 8-hydroxyquinoline. The prior art is silent with respect to whether any "means for functioning as an antioxidant" will have the same effect on stabilization of chelated 8-hydroxyquinoline.

6. Relative skill of those in the art

The relative skill of those in the art is generally that of a Ph.D. or M.D.

7. Predictability of the art

In the instant case, Claim 19 recites the limitation wherein the carrier contains "means for functioning as an antioxidant" however the Specification only provides examples of compositions containing nordihydroguiaretic acid. Ascorbic acid is also mentioned in the Specification as a potential antioxidant that can be used to stabilize the chelated 8-hydroxyquinoline in the instant composition. The Specification provides a written description and examples of the use of nordihydroguiaretic acid and ascorbic acid as antioxidants that can be used to stabilize chelated 8-hydroxyquinoline in the instant compositions but does not disclose the use of any and all structures with a "means for functioning" as an antioxidant for the same. Therefore, while there are working examples relevant to the use of nordihydroguiaretic acid in the instant compositions and its use as a stabilizer of chelated 8-hydroxyquinoline, no working examples or description regarding the use of any other antioxidant for these purposes are present in the disclosure. The nature of the invention is complex, being directed to pharmaceutical compositions with biological activity. The state of the prior art is silent

with respect to whether or not any general antioxidant or carrier with a means for functioning as an antioxidant will have the same effect as nordihydroguiaretic acid in stabilizing the chelated 8-hydroxyquinoline of the instant composition. Whether or not a particular molecule will have an effect on chelated 8-hydroxyquinoline stability is unpredictable, in that it requires empirical screening. In addition, many antioxidants are toxic and because the instant composition is a pharmaceutical composition, undue experimentation would be required to demonstrate the safety and efficacy of any particular structure or carrier with a means of functioning as an antioxidant in the instant compositions.

In view of all of these factors and the lack of description in the disclosure regarding the use of any structure with a means for functioning as an antioxidant in a composition for treating human subjects, undue experimentation would be required of the skilled artisan to practice the claimed invention.

Given the above, it is clear that the art to which the instant invention relates involves a relatively high degree of unpredictability.

8. Breadth of the Claim

Claim 19 is inclusive of any and all carriers with means for functioning as an antioxidant.

Thus, the specification fails to enable one of ordinary skill in the art to practice and use the composition of Claim 19.

5. In light of Applicant's amendments to Claims 20-21 and cancellation of Claims 51-52 dated 12/16/2005, the earlier rejection of Claims 20-21 under 35 USC § 112, First Paragraph are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Kazimierczak and Maslinski (Agents and Actions, 1974, v. 4/5, pgs. 320-323). Kazimierczak teaches a zinc/8-hydroxyquinoline complex in a 1:1 ratio (see especially Results section on p. 321). The current claims are directed to a composition containing 8-hydroxyquinoline, an escharotic chelatable metal agent and a carrier. The reference teaches a stiochiometric (1:1) complex of zinc and 8-hydroxyquinoline. The intended use is inconsequential in claims directed to a composition because patentability is assessed on the composition and not its method of use.

7. In light of Applicant's arguments dated 12/16/2005 (see especially pages 6-7 of Remarks), and especially in light of the amendments made to Claims 1 and 2 in the

same response, the previous rejection of instant Claims 1 and 2 under 35 U.S.C. § 102 is withdrawn.

Claim Rejections - 35 USC § 103

8. In light of Applicant's arguments dated 12/16/2005 the previous rejection of Claims 1-7, 14-21, 34-37, and 39-52 over WO 95/03032 (Unilever) under 35 U.S.C. § 103 is withdrawn.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James D. Anderson
Examiner
Art Unit 1614

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